REMARKS

This paper is submitted in response to the Office Action mailed September 20, 2005 for the above-identified patent application. Claims 1-4, 6-14 and 16-34 are pending in the application. Claims 6-13 and 19-33 have been withdrawn from consideration. Claims 1-4, 14, 16-18 and 34 have been rejected.

Claims 14 and 34 have been rejected under 35 U.S.C. § 102(a) as unpatentable in view of Newton *et al.*, J. IMMUNOL. 160:1427-35 (1998) ("Newton"). The Examiner acknowledges that the prior art does not teach diagnosing cancer by a process comprising detecting S100-A7 or S100-A8. However, the Examiner states that the claimed anti-S100 antibody is not limited to detecting only S100-A7 or S100-A8, but will detect the presence of any member of the S100 family of proteins.

Applicants have amended claim 14 to recite that the component for detecting the S100-A7 protein is an anti-S100 antibody *that is specific for S100-A7*. Claim 34 has been amended to recite that the component for detecting the S100 protein is an anti-S100 antibody *that is specific for detecting S100-A7 or S100-A8*. An antibody that is specific for S100-A7 or S100-A8 could not be used to detect the presence of S100-A9, or any other S100 protein, since a specific antibody is *de facto* unable to react with any other protein. Therefore, reconsideration and withdrawal of the rejection of claims 14 and 34 under 35 U.S.C. § 102(a) in view of Newton is respectfully requested.

Claims 14, 16-18 and 34 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending U.S. Application No. 10/461,424 further in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991) ("BIO-RAD").

Applicants submit herewith a terminal disclaimer, in compliance with 37 C.F.R. 1.321(c), to overcome the rejection based on the judicially created doctrine of double patenting. Therefore, reconsideration and withdrawal of the rejection of claims 14, 16-18 and 34 under the judicially created doctrine of obviousness-type double patenting is respectfully requested.

The Abstract of the disclosure has been objected to because it is entitled "Abstract of the Invention," rather than "Abstract" or "Abstract of the Disclosure." As stated above, Applicants request that the title of the abstract is amended from "Abstract of the Invention" to "Abstract."

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) as unpatentable in view of Celis *et al.*, J. UROL. 155(6): 2105-12 (1996) ("Celis"). The Examiner states that Celis discloses detecting S100-A7 in a urine sample from a subject using an immunoassay, wherein an increase in the level of the protein is an indicator of bladder cancer.

Applicants have amended independent claim 1 to recite detecting a S100-A7 protein in a sample of blood or a blood fraction. Celis does not disclose or suggest detecting S100-A7 protein in blood or a blood fraction, *e.g.*, serum or plasma, as an indicator of bladder cancer. In fact, Celis explicitly discloses that S100-A7 could not be detected in the serum of the patients studied. (*See e.g.*, Celis, pg. 2109, col. 1). Therefore, Applicants respectfully submit that, as amended, claims 1 and 2 are not anticipated by Celis. Accordingly, reconsideration and withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 3, 14, 16-18 and 34 have been rejected under 35 U.S.C. § 103(a) as unpatentable in view of Celis further in view of BIO-RAD. The Examiner states that Celis does not teach a kit comprising an anti-S100, but alleges that it would have been obvious in view of the combined teaching of Celis and BIO-RAD.

Applicants have amended independent claims 1, 14 and 34 to recite detecting the presence of a S100 protein in a sample blood or a blood fraction. As stated above, Celis discloses detecting S100-A7 in a urine sample from a subject. Therefore, Celis does not disclose or suggest detecting the presence of a S100 protein in a biological sample wherein the biological fluid is blood or blood fractions. Moreover, Celis explicitly discloses that S100-A7 could not be detected in the serum of the patients studied. (*See e.g.*, Celis, pg. 2109, col. 1). Consequently, Celis would teach one skilled in the art away from detecting the presence of a S100 protein in blood or blood fractions, as recited in the presently claimed invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 3, 14, 16-18 and 34 under 35 U.S.C. § 103(a) as unpatentable in view of Celis further in view of BIO-RAD.

Claims 1-4 have been rejected under 35 U.S.C. §112 ¶1, as failing to comply with the enablement requirement. In particular, the Examiner alleges that the invention is enabled for diagnosing bladder cancer, but does not reasonably provide enablement for diagnosing any cancer by detecting S100-A7 in any biological sample.

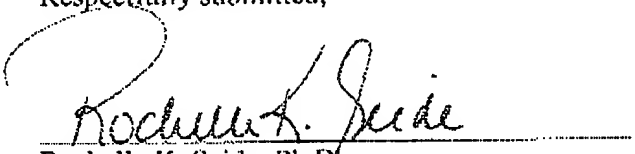
Applicants have amended independent claim 1 to recite detecting a S100-A7 protein in a sample of blood or a blood fraction derived from a subject. In addition, independent claim 1 has been amended to recite that an increase in the level of S100-

A7 protein detected in the subject's sample as compared to a control sample *is an indicator of a subject with breast cancer, lung cancer or colon cancer.* The present invention is based on the discovery that levels of S100 proteins in serum are increased in subjects with cancers, such as lung cancer or colon cancer. In addition, breast cancer cells were demonstrated to secrete an S100 protein, indicating that detection of circulating S100 proteins can be used in methods for diagnostic and prognostic evaluation of breast cancer subjects. (*See* Specification paragraph 29). In particular, S100-A7 and S100-A8 proteins were shown to be secreted by breast cancer cells. (*See* Specification, paragraphs 41 and 60). Thus, to practice the claimed method, a biological sample, such as serum (a blood fraction), is obtained from a subject suspected of having a particular cancer or suspected of being predisposed to developing cancer. A similar body fluid is obtained from a control subject that does not have cancer and the level of protein detected in the subject's sample is compared to the level of protein detected in the control sample (*See* Specification, paragraph 42). Since the specification clearly discloses the relationship between the S100 protein, the recited cancers and the method for diagnosis, it is respectfully submitted that only routine experimentation would be necessary to actually carry out the claimed invention. Accordingly, one skilled in the art could make or use the invention from the disclosure in the patent, coupled with information known in the art, without undue experimentation. Therefore, reconsideration and withdrawal of the rejection of claims 1-4 under 35 U.S.C. §112 ¶1 is respectfully requested.

In view of the foregoing remarks, reconsideration and allowance of the pending claims is respectfully requested.

A one-month extension of time for response is respectfully requested. Payment of the extension fee is to be made according to the Credit Card Payment Form attached herewith. Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300 **referencing Attorney Docket Number 108140.00014.**

Respectfully submitted,



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FEE CALCULATION

Any additional fee required has been calculated as follows:

X If checked, "Small Entity" status is claimed.

	(Column 1)	(Column 2)	(Column 3)	SMALL ENTITY			LARGE ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDL FEE	OR	RATE	ADDL FEE
TOTAL CLAIMS	32 MINUS	32	= -0-	x $25	$-0-		x $50	$-0-
INDEP CLAIMS	8 MINUS	8	= -0-	x $100	$-0-		x $200	$-0-
☐ FIRST PRESENTATION OF MULTIPLE DEP CLAIM				+ $180	$-0-	OR	+ $360	$-0-
					$-0-			$-0-

The U.S. Patent and Trademark Office is hereby authorized to charge and deficiency or credit any overpayment of fees associated with this communication to Deposit Account No. **01-2300** referencing docket number **108140.00014**.